

EPA Jacket 93182-13

Vol.2

To the Document Center (ITRMD)

*Please transfer jacket /mini-jacket to Product Manager Team circled below:

Minor Use Section PM-5

Insecticide Branch PM-10 PM-13

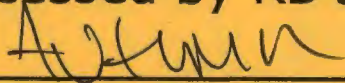
Herbicide Branch PM-23 PM-25

Fungicide Branch PM-21 PM-22

Insect /Rodent Br. PM-1 PM-7

*Reminder to PM – If applicable pick-up data from Screening Room.

Processed by RD's Completeness Check Team


(Team Member Signature)

5/19/09
(Date)

This jacket is part of
21-day screen

**Going to RD Inert Team for
Quick Review**

Jacket #: 84836-15

~~XXXXXXXXXX~~

Return jacket to Sree Nair

Date & time of drop off: 5-18-09 - 10:54 AM

Date & time of return: 5/18/09 1:20 pm

United States



Environmental Protection Agency

Office of Pesticide Programs (7505C)

Washington, DC 20460

13B5-3

Notice of Supplemental Distribution of a Registered Pesticide Product

Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product

33658-21

Distributor Company Number

11930

Note: Do not submit distributor product labels

Name of Registered Product (basic product name accepted by EPA)

Gharda Permethrin EC Termiticide/Insecticide

Distributor Product Name

Triumph EC

Name and Address of Distributor (Type; include ZIP code)

Gil Manufacturing, Inc.
PO Box 242725
Montgomery, AL 36124

Read All Conditions Before Signing

1. The distributor product must have the same composition as the basic product.
2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
4. The product must remain in the manufacturer's unbroken container.
5. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by..."; or "sold by..." to show that the name is not that of the manufacturer.
7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice.

Signature and Title of Distributor

Date

12-24-08

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrant

Date

RAM SEETHAPATHI, MANAGER BUSINESS

12/22/08

Material to be added to an e-Jacket/Jacket

Reg. No. 84836-15

Description:

1. Placement within the e-Jacket/jacket:

Default: (chronological, top = newest)

- ☐ File Location: (PDF page number, i.e., "before page 45")
-
-

2. Send to Data Extraction contractors this material:

Newly stamped accepted label

Notification

X New CSF

Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name:

REGINA FOUSHEE-SMITH

Phone: 703-605-0780

Division: RD

Date: June 30, 2009

Created June 30, 2009



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

June 30, 2009

Mr. Frank E. Sobotka, Ph.D
IPM Resources LLC (Agent)
660 Newtown-Yardley Road, Suite 105
Newtown, PA 18940

Subject: Submission of revised Confidential Statement of Formula (CSF)
Reality EC Termicide/Insecticide
84836-15
Your submission dated May 5, 2009

Dear Mr. Sobotka:

The revised Confidential Statement of Formula (CSF) dated May 5, 2009, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Acts, as amended is acceptable and have been placed in the file for the product identified above.

If you have any questions regarding this action, please contact Regina Foushee-Smith at (703) 605-0780.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard J. Gebken", is written above the typed name.

f Richard J. Gebken
Product Manager 13
Insecticide Branch
Registration Division (7505P)

DATA PACKAGE BEAN SHEET

Date: 09-Jun-2009

Page 1 of 1

Decision #: 409819

DP #: (365962)

NON PRIA

Parent DP #:

Submission #: 849724

*** Registration Information ***

Registration: 84836-15 - REALITY EC TERMITICIDE/INSECTICIDE

Company: 84836 - GHARDA GENERICS, INC

Risk Manager: RM 03 - Richard Gebken - (703) 305-6701 Room# PY1 S-7237

Risk Manager Reviewer: Regina Foushee-Smith RFOUSHEE

Sent Date:

Calculated Due Date: 05-Aug-2009

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (345) FORMULA CHANGE; TECHNICAL;

Ingredients: 109701, Permethrin(38.3%)

345
25336

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 09-Jun-2009

Due Back:

DP Ingredient: 109701, Permethrin

DP Title:

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Jun-2009

Team Name: Chem

Science Due Date:

Reviewer Name: Samir Ralsh

6/18/09

6/25/09

Sub Data Package Due Date:

Contractor Name:

7-24-09

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review amended CSF.

Thanks. Regina

PP 5-7-09

DATE OUT: 25/JUN/2009

PRODUCT CHEMISTRY REVIEW OF: AN END-USE PRODUCT [X]

DPBARCODE #: D365962 NON-FOOD USE [X] REG NO: 84836-15

PRODUCT NAME: Reality EC Temicide/Insecticide MRIDs: None

COMPANY NAME: Gharda Generics, Inc. ACTION CODE: 345

PC NO. OF THE TGAI IN THE PRODUCT: 109701 DECISION No.: 409819

FROM: Sami Malak, Chemist *[Signature]*
Technical Review Branch/RD (7505P)

[Handwritten: SBR 6/25/09]

TO: RM 13 Richard Gebken/Regina Foushee-Smith
Insecticide Branch/RD (7505P)

INTRODUCTION:

In a letter dated 05/MAY/2009 IPM Resources, LLC, an agent for the applicant requested review for acceptability a revised basic CSF for subject product, dated 05/MAY/2009.

FINDINGS:

1. The submitted revised basic CSF dated 05/MAY/2009 is substantially similar in composition to the current basic CSF dated 19/JUL/2004. Exceptions: (a) the current basic CSF, Reg. No. 33658-21, was transferred to subject product's Reg. No. 84836-15 on 03/JAN/2009; (b) product's name was changed from Gharda Permethrin EC Temicide/Insecticide to subject product's name Reality Temicide/Insecticide; (c) the current label, Reg. No. 70907-24, was transferred to subject product's, Reg. No. 84836-15 on 15/OCT/2004; (d) the source TGAI in subject product is permethrin, [REDACTED]; and (e) use of different solvents and suppliers in lieu of the currently approved solvents. No additional changes were noted regarding the nominal concentration of the AI, upper/lower certified limits or in the physical/chemical properties.
2. The submitted basic CSF dated 05/MAY/2009 will need a minor revision to change the percentage by weight of permethrin from [REDACTED]
[REDACTED]
3. All ingredients claimed in the CSF have been approved for use in pesticide formulations intended for non-food uses.
4. The applicant should be advised to change product's name listed on the label as "Gharda Permethrin EC Temicide/Insecticide" to Reality Temicide/Insecticide" for consistency with that in the proposed basic CSF.

CONCLUSIONS:

After resolving Findings 2 & 4 above, the TRB will have no objections for accepting the submitted basic CSF dated 05/MAY/2009. If and when approved, it must supersede the current basic CSF dated 19/JUL/2004. A revised label must supersede the current label approved on 21/SEP/2004.

IPM *Resources LLC*

660 Newtown-Yardley Road, Suite 105, Newtown, PA 18940 Phone: (215) 497-9501 Fax: (215) 497-9502

"an intellectual property management resource company"

May 5, 2009

VIA UPS EXPRESS

Gebken.Richard@epa.gov

[Ph: 703-305-6701]

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Richard Gebken (PM 13)

SUBJECT: Minor formulation amendment – Reality® Termiticide/Insecticide
EPA File Symbol 84836-15

Dear Mr. Gebken:

The purpose of this letter is to transmit to the Agency the subject minor formulation amendment on behalf of Gharda Generics, Inc. Please find enclosed the following:

Administrative Materials: (MRID No.: _____)

- Transmittal Form (EPA Form 8570-1).
- Formulators Exemption Statement (EPA Form 8570-27), Copy within Vol 1
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Confidential Statement of Formula (EPA Form 8570-4), Copy within Vol 1
- Confidential Statement of Formula (EPA Form 8570-4), 2 Copies/Administrative

VOLUME NO.	DESCRIPTION	OPPTS GUIDELINE REF. NO.	MRID NO.
1	Product Identity & Disclosure of Ingredients for Reality Termiticide/Insecticide [Gharda Report ID: PERM3.2EC]	Group A 830.1550	

Richard Gebken, PM 13
EPA Registrations Branch
May 5, 2009

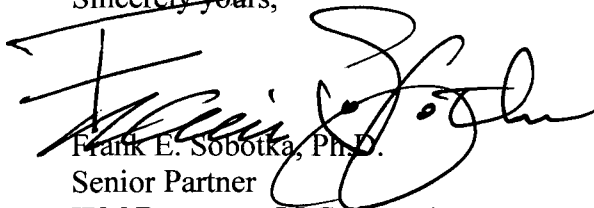
Page 2

**SUBJECT: Minor formulation amendment – Reality[®] Termiticide/Insecticide
EPA File Symbol 84836-15**

The purpose of this proposed minor formulation amendment for Reality Termiticide/Insecticide is to replace solvents in the formulation that are no longer commercially available.

If you have any questions or need additional information, please do not hesitate to contact us at any time.

Sincerely yours,



Frank E. Sobotka, Ph.D.
Senior Partner
IPM Resources LLC (Agent)

ATT:

Gharda Permethrin EC

Termiticide/Insecticide

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 21 2004

For use by individuals/firms licensed or registered by the state to apply Termiticide/Insecticide products. States may have more restrictive requirements regarding qualifications of persons using this product. Consult the pest control regulatory agency of your state prior to use of this product.

Active Ingredient
Permethrin*38.3%
Other Ingredients**61.7%
TOTAL100.0%
*cis/trans ratio: Max. 42% (±) cis and min. 58% (±) trans
** Contains petroleum distillates.
Contains 3.2 pounds permethrin per gallon as an emulsifiable concentrate.

70907-24

Transferred to
84836-15 on
10/15/04

KEEP OUT OF REACH OF CHILDREN

WARNING

PRECAUCION AL USUARIO: Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

First Aid Synthetic Pyrethroid

- IF ON SKIN OR CLOTHING:**
- Take off contaminated clothing.
 - Rinse skin immediately with plenty of water for 15-20 minutes.
 - Call a poison control center or doctor for treatment advice.
- IF IN EYES:**
- Hold eye open and rinse gently with water for 15-20 minutes.
 - Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
 - Call a poison control center for treatment advice.
- IF SWALLOWED:**
- Call a Poison Control Center or doctor immediately for treatment advice.
 - Do not give any liquid to the person.
 - Do not give anything by mouth to an unconscious person.
 - Do not induce vomiting unless told to do so by a poison control center or doctor.

FOR MEDICAL EMERGENCY: Call PROSAR 1-866-359-5660

Note to Physician: This product contains aromatic hydrocarbons, which can produce a severe pneumonitis if aspirated. Consideration should be given to gastric lavage with an endotracheal tube in place. Treatment is controlled removal of exposure followed by symptomatic and supportive care.

NOTICE: before using this product, read the entire Precautionary Statements, Conditions of Sale and Warranty, Directions for Use, Use Restrictions and Storage and Disposal instructions inside booklet. If the Conditions of Sale and Warranty are not acceptable, return the product unopened within thirty days of purchase to the place of purchase.

Gharda USA, Inc.
Newtown, PA 18940

Net Contents: 2.5 Gallons (9.69 litres)
PRODUCED IN THE U.S.A. OF U.S. AND FOREIGN MATERIALS

EPA Est. No.: 44616-MO-1

EPA Reg. No. 70907-24

Decision Information for 84836-15

Decision Seq: 409819
Action Code: 345,FORMULA CHANGE;TECHNICAL;;90

FFS Start Date
Due Date 05-Aug-2009
OPP Target Due Dt:
Negotiated Due Dt:
Registrant
Response Due Date:

Tentative Ind: No
75-Day Due Date:
FFS Original Decision:
FFS EUP Decision:
FFS Primary Decision:
Start/Stop Clock
FQPA Clock:
Days Elapsed:

Decision Status
Tracking
Create Resubmission
FFS Letters
Waiver Documentation
Action Code History

Current Status: PENDING (15-May-2009)

Decision Comments
Meetings & Milestones
Decision Ownership

Payment
FFS Information
Receipts

Unmatched Payments
FFS Negotiated Due Dates
Data Package

75 Day Letters
OPP Target Due Date
Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 849724	Foushee-Smith, Regina	84836-15	05-Aug-2009	PENDING
CSF Amendment				

21-Day Screen Completed by
Contractor

21-Day Expires on 5-28-09

Jacket # 84836-15

MRID# _____

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Transfer This Jacket to:

LINDA ARRINGTON

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 5-7-09

Experts In-Processing Signature: [Signature] Date 5/11

Fee Paid: Yes ☒

Division management contacted on issues No ☒ Yes ☐ Date _____

EPA Reg. Number: <u>84836-15</u>		EPA Receipt Date: <u>5-7-09</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent				X	X
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)				X	
	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)				X	
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)				X	

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

Studies passed 86-S review.

477502-01

Inerts approved, see CSF#

5/21/09 - Spoke with Frank Sobotka
about - two missing forms.

1) Data Matrix

2) Formulators Exemption
Statement

Contact person did not understand
why he needed a data matrix. It was
explained to him, but he still did not
understand.

5/22/09 - Left message with Frank, about the
same issues. after discussing the matter
with Supervisor. As of the 15th day
no forms were sent.

* N/A - Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/oppr001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppb001/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/oppr001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 15, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-409819
EPA File Symbol or Registration Number: 84836-15
Product Name: REALITY EC TERMITICIDE/INSECTICIDE
EPA Receipt Date: 07-May-2009
EPA Company Number: 84836
Company Name: GHARDA GENERICS, INC

FRANK E. SOBOTKA, PH.D
IPM RESOURCES LLC
GHARDA GENERICS, INC
660 NEWTOWN-YARDLEY RD, SUITE 106
NEWTOWN, PA 18940-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R340

NON-FAST-TRACK (INCLUDES CHANGES TO PRECAUTIONARY LABEL
STATEMENTS;SOURCE CHANGES TO AN UNREGISTERED SOURCE);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in blue ink, appearing to read "John L. ...", is written over a light blue rectangular background.

Front End Processing Staff
Information Technology & Resources Management Division



Pay.Gov Payment Confirmation
paygovadmin to: John Jamula

05/15/2009 11:51 AM

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Payment Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24VFJ4GA
Payment Agency Tracking ID: 74070987276

Name On Account: IPM Resources LLC
Payment Amount: \$3,444.00
Payment Date: May 18, 2009 11:51:17 AM
Account Type: Business Checking
Routing Number: 031000503
Bank Account Number: XXXXXXXXX9541
Transaction Date: May 15, 2009 11:51:17 AM
Decision Number:
Registration Number: 84836-15

Payment Needed

John Jamula to: frank_sobotka

Cc: Linda Arrington

05/08/2009 02:01 PM

Frank,

I have the amendment for Reality Termiticide / Insecticide (84836-15).

The PRIA experts have categorized this action as R340 (\$ 3,444).

Please e-mail proof of payment (check or pay.gov receipt).

If you have any questions about the category, please contact Linda Arrington.... Thanks ...JJ.

Fee for Service

^{plm} {849724=~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

3

Receipt No.

S-

849724

EPA File Symbol/Reg. No.

84836-15

Pin-Punch Date:

5/7/2009

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

—

Granted:

R340

Amount Due: \$ 3,444⁰⁰

Inerts approved - S. Rock 5/18/09

Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:

J. Miller

Date:

5/8/09

Remarks:

Receipt for Section 3

S: 849724

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration- Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 84836 GHARDA GENERICS, INC

V

Risk Manager: Registration Division, Risk Management Team 3

Product #: 84836-15

Product Name: REALITY EC TERMITICIDE/INSECTICIDE

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 05-May-2009

OPP Rec'vd Date: 07-May-2009

Front End Date: 07-May-2009

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: CSF amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

CSF

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View/Edit



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number Gharda Generics, Inc./84836-15	2. EPA Product Manager Richard Gebken	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Reality Termiticide/Insecticide	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Gharda Generics, Inc. C/O IPM Resources LLC (Agent) 660 Newtown-Yardley Rd., Suite 105 Newtown, PA 18940 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of amended confidential statement of formula for Reality Termiticide/Insecticide. Minor formulation amendment qualifying for an accelerated review. Product: Reality Termiticide/Insecticide (EPA Reg. No.: 84836-15). Contact: Gharda Generics, Inc., C/O IPM Resources LLC (Agent), 660 Newtown-Yardley Rd., Suite 105, Newtown, PA 18940 Email: frank_sobotka@msn.com Ph: 215 497-9501 FAX: 215 497-9502

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Frank E. Sobotka, Ph.D.		Title Agent		Telephone No. (Include Area Code) 215 497-9501	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Frank E. Sobotka, Ph.D.		5. Date May 5, 2009			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Agrochemical Company Ltd., C/O IPM Resources LLC (Agent), 660 Newtown-Yardley Rd., Ste 105 Newtown, PA 18940 215 497-9501	EPA Registration Number/File Symbol 84836-15
Active Ingredient(s) and/or representative test compound(s) IMIDACLOPRID	Date May 5, 2009
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) TERRESTRIAL FOOD CROP/TERRESTRIAL NON-CROP	Product Name Reality Termiticide/Insecticide

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 05/06/09	Typed or Printed Name and Title Frank E. Sobotka, Ph.D. (Agent)
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